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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/492,402

06/07/95

RAPOPORT

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HM12/1213

EXAMINER

UNBAR, S

ART UNIT	PAPER NUMBER
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1642

DATE MAILED:

12/13/99

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

3mo. 3/13/99



<b>Office Action Summary</b>	Application No. <b>08/482,402</b>	Applicant(s)	<b>Rapaport</b>
	Examiner <b>Ungar</b>	Group Art Unit <b>1642</b>	

Responsive to communication(s) filed on Sep 17, 1999

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 11-15 and 37 is/are pending in the application.

Of the above, claim(s) 37 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 11-15 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1642

✓ 1. The request filed on September 17, 1999 (Paper No. 24) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application

No. 08/482,402 is acceptable and a CPA has been established. An action on the CPA follows.

✓ 2. Claims 11-15 and 37 are pending. Claim 37 remains withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 11-15 are currently under examination.

✓ 3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

✓ 4. Because all claims are drawn to the same invention claimed in parent application Serial No. 08/482,402 and no additional arguments or amendments to the claims have been submitted, claims 11-15 remain rejected for the reasons previously disclosed in Paper No. 23, filed August 9, 1999 and all objections disclosed in Paper No. 20 filed on March 17, 1999 are maintained as follows:

***Specification***

✓ 5. The specification on page 1 should be amended to reflect the status of the parent applications.

✓ 6. The objections recited in Paper No. 12, Sections 5, 6, 7 and 8 are being maintained.

Applicant requests that these objections be held in abeyance pending notification of allowable subject matter. The objections will be held in abeyance but will be maintained because amendments addressing these objections have not been submitted.

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*Oath/Declaration*

OK 7. The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The newly submitted oath or declaration is defective because:

The residence and post office address of Inventor Rapoport were lined through and changed without being initialed.

Acknowledgment is made of applicant's claim for priority based on PCT applications PCT/US92/06283 filed 30 July 1992 and PCT/US92/07381 filed 28 August 1992. It is noted however, that applicant have not filed a certified copy of the priority documents as required by 35 USC 119.

Not  
Claimed  
in Inv.  
Decl. but

OK 8. The following rejections are being maintained

9. Claims 11-15 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 12, Section 16, pages 9-11, Paper No. 17, Section 10, pages 5-6) and Paper No. 20, Section 12, pages 5-6.

Applicant argues that (a) Examiner wrongfully applies the obviousness rejection based on hindsight, (b) there would be no expectation of success that the expression of secretable proteins would be successful in host cells other than those used in the instant invention and the prior art has not provided any expectation that the claimed invention would succeed, (c) the Lee, Ellis and Rose references are irrelevant to the instant invention because they pertain to nucleic acids, organisms, vectors and host cells that are unrelated to that of the present invention and therefore cannot be used to predict whether the truncated hTPO could be secreted, (d) the

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Lee, Ellis and Rose references do not teach or suggest a recombinant DNA sequence which encodes hTPO which is secreted from a cell, (e) even if the combined references suggested the instant invention, one of ordinary skill in the art would not expect to successfully produce a secretable protein because Rose et al and EP0139417 disclose that the protein is secreted slowly and the teachings in regard to production and secretion of the protein in any host cell could not be predictably applied to hTPO, (f) at most the references show that it is "obvious to try" the present invention and there would be no reasonable expectation of success.

The argument has been noted but has not been found persuasive because (a) it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But, so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). As clearly stated in Paper Nos 17 and 20,

the combined references teach not only the suggestion but also the means and motivation to successfully produce a recombinant DNA encoding a secretable human thyroid peroxidase, (b) Applicant is arguing limitations not recited in the claims as currently constituted, however, it is clear that the CHO cells used for the expression of secretable protein in the instant invention was well known in the art as EP 0139 417 clearly used the CHO host cell system for the expression of recombinant cDNA encoding secretable protein, © as drawn to vectors and host cells, Applicant is arguing limitations not recited in the claims as currently

constituted but as drawn to nucleic acids and organisms that are unrelated to the present invention, regardless of nucleic acids and organism involved, the references clearly teach the production of secreted proteins by transfecting host cells with cDNA encoding truncated protein as well as the advantages of secreted proteins thus one of ordinary skill in the art would have expected to be able to successfully produce secretable truncated proteins in view of the cited references, (d) applicant is arguing the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); *In re Keller* 642 F.2d 413,208 USPQ 871 (CCPA 1981). Clearly, the DNA sequence of human thyroid peroxidase was well known as shown by the cited references and further the transmembrane domain of the porcine thyroid peroxidase was known and it was clearly within the purview of one of ordinary skill in the art to use conventional hydrophobicity plots to determine the transmembrane domain of the known sequence of human thyroid peroxidase, (e) as drawn to the speed of secretion, Applicant is arguing limitations not recited in the claims as presently constituted and for the reasons set forth above, one would have a reasonable expectation of success producing the secretable protein, (f) more than showing that it is "obvious to try", for the reasons set forth above, the combined references provide the suggestion,

means and motivation to successfully produce a recombinant DNA encoding a secretable thyroid peroxidase for the reasons disclosed in Paper Nos 12, 17 and 20.

10. All other objections and rejections recited in Paper No. 20 are withdrawn.
11. No claims allowed.
12. This is a CPA of applicant's earlier application S.N. 08/482,402. All claims are drawn to the same invention claimed in the earlier application and, although applicant has filed request for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d), no Amendment or Response containing either arguments drawn to the instant rejections or amendments to the claims has been submitted. Thus, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). See M.P.E.P. § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

*Susan Ungar*  
Susan Ungar  
Primary Patent Examiner  
December 9, 1999